June 7, 2017

Marlene H. Dortch, Commission Secretary
Office of the Secretary, Federal Communications Commission
FCC Headquarters
445 12th St. SW., Room TW-A325
Washington, DC 20554

Re: FCC Public Notice: FCC Seeks Comment and Data on Actions to Accelerate Adoption and Accessibility of Broadband-Enabled Health Care Solutions and Advanced Technologies (GN Docket No. 16-46)

Dear Marlene H. Dortch,

Baxter International Inc. ("Baxter") is pleased to have this opportunity to submit comments to the FCC Public Notice: *FCC Seeks Comment and Data on Actions to Accelerate Adoption and Accessibility of Broadband-Enabled Health Care Solutions and Advanced Technologies*. Baxter provides a broad portfolio of essential renal and hospital products; including home, acute and in-center dialysis; sterile IV solutions; infusion systems and devices; parenteral nutrition; surgery products and anesthetics; and pharmacy automation software and services. The company's global footprint and the critical nature of its products and services play a key role in expanding access to healthcare in emerging and developing countries. Baxter's employees worldwide are building upon the company's rich heritage of medical breakthroughs to advance the next generation of healthcare innovations that enable patient care. Our company mission is to save and sustain lives and we support the efforts the FCC is seeking comment on, in order to accelerate accessibility of health care solutions and advanced technologies.

We appreciate the opportunity to comment on this public notice and provide recommendations for your consideration. We respectfully submit the following comments:

General Comment: Reliable, secure, high-speed, high-bandwidth, low-latency broadband access is critical to enabling access to care and modern healthcare technologies. Additionally, guidance, tools, and regulatory policies that facilitate rather than inhibit the use of broadband networks are very important. As healthcare organizations transition from wired to wireless, and as data moves from within an organization's private network to the broadband network, the cybersecurity, privacy, legal, and other risks grow. Costs and usage are directly impacted by those risks, and those risks potentially can stifle the innovation and execution that lead to better patient outcomes. With the right infrastructure, guidance, tools, and policies, we can increase access to great care for those who need it without sacrificing safety, privacy, or innovations in patient care.

OBJECTIVE I: Promote effective policy and regulatory solutions that encourage broadband adoption and promote health IT.

2. We request information and data on the types, impact, scale, and benefits of broadband-enabled services and technologies used for the delivery of health care. How is broadband *currently* being used to augment or transform existing health care delivery? What types of health care settings are using broadband-enabled services and technologies besides large medical hospitals? What variety of medical issues are they used for? Where are these health care settings located? What are some of the *future plans* for using broadband-enabled health services and technologies – not just by clinicians and hospitals but also by other participants in the broader health ecosystem?	Broadband is used with technologies that support management, diagnosis, treatment and coordination of care for patients with many medical issues, both acute and chronic. It is currently used throughout hospital centers to support the delivery of renal care for treatment of hemodialysis (acute and chronic) and infusion therapy. In this setting, broadband enables communication of hospital systems and devices which share patient data, which enables the coordination of patient care between care givers. In the outpatient setting, broadband is utilized in hemodialysis and infusion clinics as well as in the home setting where patients use broadband connections in conjunction with their peritoneal dialysis and infusion devices while they receive therapy. Broadband is a part of the broader healthcare ecosystem which enables care, allowing for scheduling of appointments, contact with care givers (internet enabled-phones), IoT devices for monitoring biometrics and other devices which demand broadband for participation in healthcare. Additionally, suppliers of healthcare make extensive use of broadband in managing their supply chains, communicating with their customers, the patients that they serve on behalf of their customers, as well as with the suppliers that enable them to deliver innovative and life extending therapies and solutions. Broadband-enabled services are used in all healthcare settings extending beyond large hospitals including small community hospitals, rural clinics, outpatient treatment centers, specialty clinics (e.g. dialysis and infusion clinics), pharmacies, as well as in primary care facilities. These healthcare settings are located across all areas of the United States, although the availability of broadband networks is not always present. This is particularly true in remote rural regions of the United States. In these regions, healthcare providers – particularly those with specialty care experience – are not common and the need for broadband enabled technologies to support remote care is required.

| 3. We are also interested in learning how health technologies and services can take advantage of new technological applications and emerging communications networks. For example, what impact will the Internet of Things (IoT) have on broadband-enabled health technologies and services such as telehealth and telemedicine? To what extent will pervasive connectivity and a fully connected environment around individuals (e.g., IoT) shift the point of care delivery? How might the demands on broadband networks evolve in this new environment? What, if any, changes are anticipated in existing broadband-enabled health services and technologies—operating over current mobile networks—when 5G (Fifth Generation Mobile and Wireless Networks) becomes available? To what extent might telehealth and telemedicine be impacted by the availability of 5G networks? What medical device innovations are anticipated to be developed using 5G networks? | Internet of Things (IoT) will have an impact on telehealth and telemedicine by enabling a broader set of diagnostic tools to be used within the patient's home and allowing more of the doctor's tool kit to enter the patient's home without the doctor setting foot in the front door. Prior to the proliferation of IoT, a doctor practicing telemedicine would only be able to consult with the patient by having a conversation and perhaps be limited to visual and auditory cues. Now, with IoT, the doctor can gain numerous data insights since the patient can capture their weight, blood pressure, temperature, oxygen, etc., through use of devices at home.

Pervasive connectivity is one part of the equation. It is a requirement for adoption, but there must also be wide-scale clinical belief (usually via clinical evidence) to shift the standard of care from one point of care to another point of care (e.g. shift of in-patient surgery to outpatient surgery). There must also be a highly engaged patient in order to make the system work. For example, if a healthcare provider requires a patient to take weight measurements via an IoT scale, the patient must be engaged enough to step on the scale each day. Lastly, for the system to really work there must be reimbursement for the provider. |
| 4. What technical issues concerning the variety of broadband-enabled health care solutions and technologies are appropriate and necessary for the FCC to consider with respect to efforts to accelerate broadband adoption and promote health IT solutions? Are there issues of concern with respect to access, availability, interoperability, capacity, reliability, privacy, security, and speed? If so, please describe them. Does consideration of any of these issues vary depending on the technology platform—e.g., digital subscriber line (DSL), cable, fiber, wireless, or satellite? | There are numerous issues with respect to interoperability, privacy and security.

Interoperability – In healthcare, there is technical challenge due to a fractured set of standards for coding, terminology, transfer, billing, diagnosis and other purposes (e.g., ICD-9, ICD-10, SNOMED-CT, HL7, and FHIR). While there is a desire to align toward single standards for data transfer and coding, this has not yet been achieved. Federal agency support towards harmonization of these standards would help to address this technical challenge. This issue is independent of provider line; however each standard may be of varying importance to different healthcare provider or recipient (e.g. large hospital versus small clinic versus patient home).

Privacy – This is a complex and rapidly changing space which will certainly evolve. Privacy is encompassed within HIPAA requirements, and interpretation of these requirements should account for the continuing evolution of technology and patients' increased acceptance of analytics and mobile devices.
Security – Increased security concerns will continue to arise in light of hacks and data breaches of patient health data. This is increasingly important with the |

	increase in broadband and web based technologies that are prone to brute force attacks and other common threats that are increasingly common.

Cybersecurity – Manufacturers should design cybersecurity controls into their medical devices, with the assumption that the device could be placed on a hostile network. If endpoint controls are working effectively, it should not matter whether broadband (or any other technology) is used to deliver health care solutions. |
| 5. We seek to better understand health care providers' connectivity requirements. What type of connectivity (e.g., wired or wireless; fixed or mobile) is necessary to support the deployment of health IT applications today and in the near future at the different types of health care delivery settings (e.g., tertiary care centers versus primary care physician practices, larger physician groups, clinics, hospitals, as well as "hospital in the home" settings).

a. What are the minimum bandwidth and speed requirements for the different types of health IT applications available today and in the near future for clinical and non-clinical settings? We also seek comment on bandwidth constraints brought on by increased overall usage as well as the impact of data intensive medical applications. Are there future technologies or applications on the horizon that could be bandwidth intensive? If so, what are they, and to what extent could compression and other technologies provide a solution for such future technologies or applications?

b. Some evidence suggests that real-time image manipulation and video (e.g., telestroke and tele-emergency applications) will stimulate demand for more and better broadband and at lower prices. Are there current issues concerning network speeds and delays for these types of services? Do mobile health applications present unique considerations in terms of coverage, reliability, and security? We seek suggestions on whether, and if so, how the Commission could address these issues.

c. To what extent do rural communities and Tribal lands have access to Internet connection speeds that are sufficient to support the effective and efficient transmission of data and video to provide telehealth, telemedicine, and other broadband health technology services?

d. What, if any, interoperability, capacity, reliability, security, and speed issues currently exist for wireless (i.e., radiofrequency (RF)-based) medical | Healthcare providers have a variety of IT systems – all of which are not always the most "up-to-date" systems available. Additionally, there may be a number of challenges in adoption of certain platforms for use based on IT requirements for a healthcare provider in a large hospital setting (e.g. iOS) versus in a small clinic. The deployment of health IT applications may be a simple process in a small private clinic or tertiary care center, but may take many weeks and require significant resources in a large complex hospital to ensure that the introduction of the application does not introduce into the IT system a problem which could cause significant damage. Because of the scale of these larger hospital systems and the amount of data that typically is "flowing through the pipes" of these institutions (e.g. from radiology, cardiology, etc.), the connectivity requirements are much more significant than in a smaller hospitals and require greater variety of fixed, mobile, wireless deployments to support a variety of uses by clinicians and patients.

    a. The greatest bandwidth and speed requirements will likely be required from enterprise distribution of medical images. These use cases require transmission of enormous datasets for the purpose of medical interpretation. In the future, these will likely remain the largest datasets in healthcare IT, particularly as the complexity of these images increases.
Advanced visualization applications and Virtual Reality Applications in medicine may impact intensive bandwidth usage, particularly if these applications are dependent on infrastructure that requires datasets to be pushed and pulled from a server that is cloud-based. Compression technologies may provide an answer for these use cases (along with the correct architecture) so that these technologies do not impede the performance of other |

devices used by patients in both clinical and non-clinical settings (e.g., at home); and for healthcare providers with respect to the provision of broadband-enabled health technologies, like telehealth and telemedicine services? Are there other technical issues appropriate for the Commission to consider?

e. What impediments, if any, exist in trying to retrofit existing and future health care facilities (e.g., hospitals and clinics) for broadband-enabled services and technologies, given current connectivity needs and the existence of varied spectrum environments? Do current designs take into consideration any potential interference concerns with projected wireless networks and devices that will be used in these facilities? Are there (or should there be) industry standards or best practices for ensuring that new health care facilities consider broadband in their design and account for any necessary conduits, wiring, building configuration, and materials (e.g., there may be a need to consider certain materials for internal or external walls to better enable wireless broadband within a facility or to limit RF into a building) at the design and construction phase?

enterprise applications.

b. In some applications and devices that are used for clinical decision making in real-time, delays in network speed can have adverse effects to patient outcomes or disrupt clinical efficiency and workflow. Where patient outcomes are critical (e.g. tele-emergency), back-up support for networks and redundancies are required to ensure data is not lost and that there are no disruptions during patient diagnosis or treatment. In less clinically significant applications, network speed may be a lesser issue – so long as the data is transmitted eventually. Therefore, a precise understanding of the criticality of the data for patient care is necessary to determine the potential impact of network speed.

   MHealth applications have considerations in coverage, reliability and security. In all of the above, there are dependencies not only in the software but in the telecom provider, the mobile device manufacturer and in the operating system/s (and other code base) the application resides on. All of these can represent potential compromises in coverage, reliability and security.

d. In some RF-based medical devices there are limitations in some hospital environments due to large quantities of metal (e.g. orthopedic devices, surgical equipment). For example, with passive RFID tags, the signals may not work well in such an environment. Active RFID alternatively would "do better" – but might be significantly more costly – and may not necessarily be the right solution for all applications. Passive RFID tags may require extensive WIFI networks to operate successfully, which may represent significant infrastructure changes in large hospital systems.

e. Some hospitals have existing infrastructure which is very old and requires significant build-out in order to support upgrades to IT that will enable development of stronger broadband applications. In some cases, particularly in urban centers, some facilities may be very old buildings that were not designed for modern healthcare (e.g. New York City hospitals have some facilities that were built in the 1880s). Likewise, patient populations in urban centers may face similar

	challenges in deploying broadband in older infrastructure – or be limited by the number of available providers (e.g. Satellite not available, Cable not available, Fiber not available, only DSL connections). In rural centers, access to broadband may be limited by the lack of infrastructure that can support high speed networks. Some devices will have considerations in their design specifications regarding interference which would need to be offset to reduce the impact of device error or malfunction, adverse event or other unintended consequence in use. These industry standards often exists in the design and construction associated with medical imaging systems used in radiology, such as magnetic resonance imaging where RF shielding is built around the device for proper device function as well as operator and patient safety. Other environments may also include shielding of some type (e.g. surgical suites or operating rooms) if radiology equipment is used in the environment. This shielding is used to prevent excess scatter radiation but may impact RF capabilities in devices given the large presence of metal used. Since these components are constructed in the capital purchase cycle of large equipment, it is unlikely these pieces will move for deployment of broadband solutions – but rather the broadband solution would need to work around this existing infrastructure. In urban centers, additional considerations for RF may include areas where there is close proximity to traffic or other large metal objects as they may disrupt or alter signals from RF generating or receiving devices.
6. We seek to understand the full range of issues that might be affecting the development and adoption of broadband-enabled technology and services in health care. What non-technical impediments or issues currently exist in the provision of broadband-enabled health technology services? Are there any circumstances or practical considerations (e.g., cost, funding, and training) that may be creating disincentives for clinicians and health care settings to offer broadband-enabled health services and technologies, such as telehealth and telemedicine? If so, please describe what they are, including the extent and nature of	One major disincentive for clinicians remains reimbursement and lack of evidence around the outcomes with these solutions in many applications. Firstly, in healthcare in the United States, reimbursement is still largely geared towards episodic care rather than continuous models of care, which telehealth and remote patient monitoring as categories (enabled by broadband) support. Few health systems incentivize this type of care – with few reimbursements for use of the technology. For those payers that do provide reimbursement for telehealth or remote patient monitoring, often it is at a lower rate than the in-clinic visit, which may

the Commission's authority to address them.	disincentive adoption of these solutions from an economic standpoint. That said, some thought-leading physicians are recognizing the opportunity in stratification of their patient populations and treating more patients overall – with less severe patients in the remote setting and more severe in the clinic. For those patients that are medically stable and can be managed in the home, clinicians should be eligible for reimbursement of treatment through telehealth or telemedicine, which includes remote patient monitoring and in home care. Another disincentive is in the lack of clinical evidence for the broad range of solutions enabled by broadband. For some clinical areas, there is some robust data starting to appear (e.g. cardiology). For most areas in chronic disease management, there are generally only key opinion pieces, case studies and cohort studies that represent the bulk of the clinical literature for clinical outcomes. There are few (if any) multi-center, randomized controlled trials using these technologies that can show strong evidence of their clinical efficacy with strong statistical association. As a result, there are generally no standard recommendations from clinical associations on use of these technologies in the standards of care protocols for management of specific chronic diseases (e.g. use of mHealth applications in the management of initial onset Type-2 Diabetes in contrast to pharmaceutical guidelines around use of the drug Metformin for initial onset of Type-2 Diabetes). An important nontechnical payment policy change would be to allow a patient's home and the dialysis facility to be originating sites for telehealth purposes for Medicare reimbursement. Medicare requires that the patient setting, termed the "originating site," be a clinical site such as a doctor's office or hospital. Multiple congressional efforts have focused on expanding Medicare payment and demonstrating the clinical and financial value of serving this population through telehealth technologies. Removing this barrier to access would expand access to dialysis services to those with limited options in terms of geography, modality choice, or both. Today the number of Americans living with end-stage

renal disease (ESRD) represents a ten-fold increase from what it was in 1980[1], and it will likely increase further, as an estimated 26 million people in the United States have chronic kidney disease and are at risk for kidney failure. Due to the limited number of kidneys available for transplantation, the clear majority of ESRD patients, approximately 70 percent, depend on dialysis to replace kidney function.[2]

Home dialysis—peritoneal dialysis (PD) and home hemodialysis (HHD)—is an important treatment option that offers patients significant advantages, including clinically meaningful improvements in physical and mental health. PD patients may experience fewer negative side effects, such as nausea, and dietary restrictions than in-center patients.[3] Additionally, home dialysis offers significant advantages, including greater autonomy and flexibility in dialysis scheduling, and reduced dependence on transportation.

Lengthy trips to a facility multiple times a week have the potential to interfere with a patient's work and personal life. Research shows that after six months of in-center hemodialysis, only 43 percent of people can maintain the same level of employment as before they began treatment. This means that over half of all in-center dialysis patients are unable to maintain the same level of employment.[4]

Despite the advantages of home dialysis, today only 11.5% of U.S. dialysis patients receive treatment at home, with approximately 9% of patients receiving peritoneal dialysis and less than 2% of patients receiving HHD.[5] **Congress' stated intent in the creation of the ESRD benefit was that "the maximum practicable number of patients who are medically, socially, and psychologically suitable candidates for <u>home dialysis</u> or transplantation should be so treated."[6]** (Emphasis added). In its October 2015 report, "Medicare Payment

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[1] U.S. Renal Data System. ESRD Quarterly Update – July 2016. Available online www.usrds.org.

[2] The Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy, Chapter 6, "Outpatient Dialysis Services". Washington, DC: MedPAC, March, 2014. Web. http://www.medpac.gov/documents/Mar12_EntireReport.pdf

[3] "A Brief Overview of Peritoneal Dialysis." DaVita, Inc., Web. 16 Jul 2012. http://www.davita.com/treatment-options/home-peritoneal-dialysis/what-is-peritoneal-disease-/a-brief-overview-of-peritoneal-dialysis/t/5483.

[4] Rebecca J. Muehrer, Dori Schatell, Beth Witten, Ronald Gangnon, Bryan N. Becker, and R. Michael Hofmann, "Factors Affecting Employment at Initiation of Dialysis," Clinical Journal of the American Society of Nephrology 6, no. 3 (March 2011)

[5] U S Renal Data System, USRDS 2016 Annual Data Report.

[6] Section 1881(c)(6) of the Social Security Act.

	Refinements Could Promote Increased Use of Home Dialysis", the Government Accountability Office (GAO) estimated that up to 25% of dialysis patients could realistically dialyze at home. Telehealth services can help achieve this objective by providing a framework for safe, reliable patient/practitioner interaction. Permitting patients and their physicians the option to participate in telehealth visits in lieu of face to face visits some months may incentivize patients to adopt home dialysis as a treatment option. Such telehealth interactions are appropriate when they 1) include a video interaction, 2) are supported by the transmission of clinical data that facilitates physician review and evaluation of patient treatment, and 3) are compliant with federal and state laws protecting privacy of patient health information. With this change, patients would no longer have to travel to a hospital or facility-qualifying site to interface with an approved practitioner. This task is oftentimes difficult for dialysis patients and may act as a disincentive to adopt home dialysis as a treatment option.
7. What efforts are being made at the state and local levels to address broadband health technology accessibility issues in rural and remote areas, Tribal lands, and underserved urban areas? We seek specific information, particularly from states, localities, Tribal governments, and rural and urban medical centers, about any broadband-enabled health IT programs that have been developed and implemented (or will soon be implemented) to reach these areas. How successful have those programs been? What are some of the lessons learned in developing those programs? What programs and other efforts are necessary to drive attention to those rural and underserved populations that need health technologies most? How can the Commission better facilitate the deployment of services and technologies as well as consumer adoption in those areas?	Some companies are looking at use of remote patient management solutions in the support of rural Native populations in the Arctic Circle for the care of ESRD, which will help to avoid the costs associated with patient travel to caregivers in urban centers for consultations (or caregiver costs of travel associated with travel to provide care to these remote indigenous populations). These programs are still very new and in the pilot and exploratory phases.

OBJECTIVE II: Identify regulatory barriers (and incentives) to the deployment of RF-enabled advanced health care technologies and devices.	
10. We seek information on the types of broadband-enabled health technologies and medical devices that are *currently* in the market. In addition, what emerging types of broadband-enabled health technologies and medical devices are likely to be available to consumers *soon*? What are the *future* trends in this market area?	The market currently has a wide variety of consumer facing wearable devices for capturing data, most notably for activity monitoring, but also additional applications of glucose monitoring, weight measurements, body temperatures, oxygen levels in the blood, and blood pressure. Increasingly, newer devices are coming into the

	market with claims of greater accuracy, and medical device companies are offering a broader spectrum of devices that are broadband-enabled. In addition, software products that allow for capture of data from multiple sources (e.g. wearables, lab reports, electronic medical record (EMR), or genetics) are offered as personal insight tools which leverage broadband and web browsers for viewing of health data. Increasing trends in this market area will certainly include a greater influx of tools for single source viewing of health data viewing (e.g. Mint for all health data across multiple health providers), telemedicine and remote patient monitoring for chronic diseases and prescription management. Baxter's Automated Peritoneal Dialysis (APD) cycler, AMIA, was cleared by the Food and Drug Administration (FDA) in October 2015, to provide PD to patients with End-Stage Renal Disease. The AMIA APD system was developed to support home PD therapy to patients and provides an important treatment option for patients with kidney disease who are self-managing the disease with home-based therapy. New features incorporated into the AMIA APD cycler with SHARESOURCE increase the efficiency of training beneficiaries and enable patients to conduct their own PD therapy. The AMIA APD system with its SHARESOURCE platform provides two-way web-based remote connectivity with physicians, allowing treating nephrologists and clinics to remotely monitor a patient's treatment data and manage their care by reprogramming the cycler in between monthly clinic visits. The system features on-demand access to timely, accurate historical treatment data, and three user portals (clinical portal, customer service portal, and patient portal) which enable information-sharing between patient and clinician. These new features allow clinical decisions to be made in a more timely and accurate manner.
11. What, if any, technical issues or concerns exist for patients and other users of medical devices when such devices are used in hospital settings? Do these concerns vary depending on the type and size of the hospital setting? Are these concerns exacerbated when medical devices are operating in large or busy hospital environments (which may include a wide variety of wireless technologies, some of which may be unrelated to clinical care); if	See response to question #4 above. Many of the major technical concerns will rely on interoperability, privacy, security and cybersecurity. In large hospitals and mid-sized hospitals, as well as in many physician practices the above technical issues need be considered. In smaller centers, clinics and ambulatory facilities, particularly those without EMR adoption, or limited IT infrastructure, these issues will not be major technical concerns.

so, what are those concerns, how can they be addressed?	In a larger hospital setting, there would be more concern on the interoperability of the various medical devices saturating the frequency spectrum, which in turn would impact the effectivity of the device and its efficacy. Interoperability guidance (i.e. KDB) from FCC on how medical devices should be tested to ensure compliance would be welcomed. Medical device manufacturers must still take accountability for their devices in their intended use environments. A draft plan from FCC on how to support possible new technology or spectrum used is being sought. On the other hand, in a rural hospital setting, is it forecasted that a saturation of adequate bandwidth to accommodate existing medical devices can occur.
13. We seek comment, data, and any studies on the possible complexities of the future RF environment in homes, hospitals, and other public spaces related to the increasing number of medical applications and devices.	Availability of bandwidth given the proliferation of wireless enabled devices, both medical and non-medical, in densely populated and occupied areas (both regions and individual buildings) is a growing issue. Even for the most advanced hospital centers, keeping pace with bandwidth and quality of service needs for medical devices is challenging. Consider the introduction of wireless enabled infusion pumps into a large hospital, where the number of pumps can exceed 1000 devices. This level of increase in devices requires careful planning of network infrastructure improvements to accommodate. Additionally, RF noise sources are proliferating as IoT consumer application and other uses of RF expand, placing burdens on care providers and medical device manufacturers to ensure safe therapeutic operation of wireless medical devices. Hospitals in particular need tools and expertise to build and monitor their wireless infrastructures and RF environments to ensure safe and reliable operation of wireless medical devices.
15. We also request recommendations on how the Commission could make an assessment of the spectrum and wireless infrastructure needs for the future of health care in the United States. We seek input from all relevant stakeholders, including members of the health care, wireless, and software industries who are developing wireless healthcare applications for the present and future; physicians, consumer advocates, and academicians; and relevant federal, state, and local government agencies. While we envision building upon the spectrum management and wireless infrastructure deployment policies that the FCC has successfully employed in the past to promote innovation in wireless health services, we ask commenters to identify any novel framework, including those that	a. The increased availability of health apps and connected edge devices will push the health industry towards prioritization of major initiatives in interoperability, security, privacy, platform services, Open APIs, and data analytics. c. Small hospitals in some cases are more resource constrained and in some cases becoming ancillary facilities tied to larger facilities as feeders for primary care for the specialized larger centers. As stand-alone hospitals, they often have fewer support staff, lower operating margins, fewer capital budgets and a smaller scope of clinical services that they can offer.

might include smart city initiatives or public/private partnerships, that could be useful in planning for the wireless future of our nation's health care system.

a. One of the compelling drivers of mobile technology in healthcare is the increasing availability of health apps for smartphones and tablets. There is now an app for almost every conceivable healthcare need, ranging from drug dose calculators to fully functioning electronic medical records. We are also seeing the development of smart homes and automobiles that would enable even more sophisticated remote health monitoring. How soon will we see widespread adoption of these technologies and what implications will they have on the spectrum needs of the health care industry?

b. In developing a national spectrum plan for the health care industry, are there particular spectrum bands that the FCC should consider?

c. When it comes to increased need for spectrum-based health technologies, what challenges do small, rural, and critical access hospitals have that are different from what large hospitals face?

d. Do health care facilities, because of their different physical characteristics, require different types of small cells and wireless infrastructure than other commercial enterprises? What are the most challenging impediments to the deployment of wireless infrastructure in hospitals and health care systems? What policies should the FCC consider in order to help streamline infrastructure siting that is necessary for the deployment of wireless networks in hospitals and health care systems? What state or local government regulatory policies have helped to facilitate streamlined deployment of wireless infrastructure for health care?

e. How can new advanced spectrum sharing techniques (e.g., dynamic spectrum sharing through database controlled coordination, software designed radios, or efficient spectrum use through network virtualization techniques) or secondary market mechanism (e.g., spectrum leasing arrangements) be leveraged to meet the spectrum demands of cutting-edge mobile broadband-enabled health technologies and medical devices that may be operating in varied spectrum environments? Are there any issues with harmonization of spectrum for medical uses across international borders to ensure that consumers can effectively and safely use medical and other devices across borders?

f. What are some of the recent and emerging

trends in health care delivery (in rural and urban areas) that are implicating spectrum use and needs? Are these trends creating a greater need for spectrum wireless services, particularly in rural areas? Are these trends resulting in increased use of remote patient monitoring solutions?	

OBJECTIVE IV: Raise consumer awareness about the value proposition of broadband in the health care sector and its potential for addressing health care disparities.	
26. We request information on any studies, pilots, research, or other data that quantifies the benefits of broadband-enabled health technologies in improving patient outcomes and in reducing costs. What kind of return on investment have pilot and demonstration projects experienced?	There have been very few large, randomized controlled studies that have demonstrated the clinical benefit of technologies such as wearables and telemedicine. There have been many case studies and cohort studies that have demonstrated benefits of these technologies in a variety of clinical areas, e.g. cardiology[7] and diabetes[8].
27. We are interested in learning how broadband can enable healthcare-related support systems to connect patients to the people, services and information they need to get well and stay healthy. In this regard, physicians inform us that there is growing recognition that the need for social services and supports (e.g., nutritionists, dieticians, pharmacists, family caregivers, fitness centers, and other health care supports or supporters outside the traditional hospital setting) significantly impact the ability of some consumers to become healthy and stay well, and that the availability of broadband is increasingly essential to bridging the various services and supports. We seek comment and suggestions on how the Commission can support the development and availability of these new broadband-enabled services and supports (outside the RHC Program) especially on Tribal lands and in rural, remote, and other underserved areas?	Tools that enable collaboration among care givers should be a major driver in the management of coordinated patient care with broadband enabled technology. For chronic disease management, this means that the data and information must be aggregated and delivered in the right way, with the right clinical context to the right clinician, securely to inform clinical decision-making in a timely manner that will support reduced cost of care and better clinical outcomes.
29. Are there any practical issues (e.g., the lack of a home computer) that may be impeding consumer awareness and adoption of broadband-enabled health technologies? What efforts can be undertaken to help alleviate some of these issues?	Some patients will struggle with the required technology to enable use of broadband technology in the management of their healthcare. This is particularly true in older patients who may not have access (or have limited capability to operate) recent versions of Smart devices in conjunction with IoT devices in a modern ecosystem of patient biometric data collection. Simplification in user interface design, specific devices created for populations of

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[7] Dekker LR, Pokushalov E, Sanders P, Lindborg KA, Maus B, Pürerfellner H. Continuous Cardiac Monitoring around Atrial Fibrillation Ablation: Insights on Clinical Classifications and End Points. Pacing Clin Electrophysiol. 2016 Aug; 39(8):805-13. doi: 10.1111/pace.12897. Epub (2016 Jun 19). PMID: 27226200

[8] Wang G, Zhang Z, Feng Y, Sun L, Xiao X, Wang G, Gao Y, Wang H, Zhang H, Deng Y, Sun C. Telemedicine in the Management of Type 2 Diabetes Mellitus. Am J Med Sci. 2017 Jan; 353(1):1-5. doi: 10.1016/j.amjms.2016.10.008. Epub (2016 Oct 27). PMID: 28104096

	older, less-technically savvy patients and "auto-integrated" edge devices will ease the transition to the new world. Less reliance on Bluetooth and Wi-Fi in lieu of Mobile Networks may be a better alternative for ease of use and reliability.

OBJECTIVE V: **Enable the development of broadband enabled health technologies that are designed to be fully accessible to people with disabilities.**

30. How are broadband-enabled health technologies and medical devices currently being used by people with disabilities? To what extent can these technologies and devices address the health care needs of people with disabilities in the future? Provide specific examples of the existing barriers, if any, that these technologies and devices pose for people with disabilities.	Broadband-enabled technologies and medical devices are currently being used by people with disabilities for the management of chronic diseases. These are most commonly used with patients with Diabetes Type-1 and Diabetes Type-2, where patients use glucose monitoring either acute or continuous for measurement of blood glucose. Increasingly, these measures are aggregated with other patient data including other biometric data (body weight, temperature, blood pressure, lab values) for a more comprehensive picture of the patients' overall health. For some patients with disabilities, there are significant challenges associated with coordination of care across multiple caregivers, management of patient records, access to care (when living remote). Telehealth and remote patient management can help solve many of these issues.
33. We seek suggestions as to how the Commission can effectively raise awareness among people with disabilities about the value proposition of broadband in health? How can the Commission help to enable the adoption and accessibility of such services and technologies among people with disabilities, especially given our authority?	The Commissioner could partner with industry leaders and patient advocacy groups to educate people about the value in management of early-onset chronic diseases through use of broadband-enabled technologies. Management of early-onset disease (e.g. pre-diabetes) through these technologies could provide improvement in quality of life versus disease progression (e.g. pre-diabetes could progress into diabetes, heart disease, cancers, etc.). Patient advocacy groups can educate patients & clinicians about new technologies and alternatives they may not be aware of that may help them manage patient health.

OBJECTIVE VI: Highlight effective telehealth projects, broadband-enabled health technologies, and mHealth applications across the country and abroad—to identify lessons learned, best practices, and regulatory challenges.

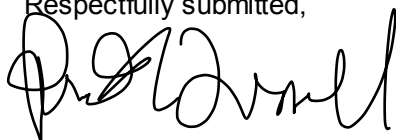| 34. We seek current information and data on the effectiveness of broadband-enabled telehealth and telemedicine services, including any recent research on these services. How are patients responding to these services? We are particularly interested in receiving comments directly from	Current users of telehealth technologies in end stage renal disease (ESRD) provide positive feedback about the use of the technology in maintaining contact with their caregivers while remaining in the comfort of their homes.

consumers about their experience with these and other broadband-enabled services and technologies.	"No matter where you are Sharesource is with you. It's knowing you have that guardian angel over you so if you have problems, you've got it covered. It's okay." -Patient in rural Nebraska using Baxter's Amia with Sharesource for peritoneal dialysis & remote patient monitoring. The technology allows patients to have access to a more conservative therapy for their treatment of ESRD.
36. We seek comment on how the public can be better informed about the availability of broadband-enabled health services and technologies and mHealth applications. What have states, localities, other federal agencies, Tribal governments, and hospitals and clinics done to inform the public about the availability of these options? How effective have these projects been in promoting greater broadband utilization?	MHealth applications and broadband-enabled technologies have largely been introduced by companies with focus in medical devices with portfolio solutions that are tied to chronic diseases. In some cases, these devices or applications are tied to larger solutions of products for care of chronic diseases (e.g. cardiac care). In other cases, mHealth applications are tied to delivery of patient information. Most of the promotion or awareness around these solutions is created by the manufacturers of these devices and applications. MHealth applications have seen significant levels of adoption however; the level of penetration of these applications has not nearly reached the potential that exists.
37. We seek submissions of any case studies, research and video/audio summaries concerning recently launched applications/programs that are on the cutting edge of telehealth, telemedicine, mHealth, and other broadband-enabled health technologies and services.	See response to question #10 above.

OBJECTIVE VII: Engage a diverse array of traditional and non-traditional stakeholders to identify emerging issues and opportunities in the broadband health space.	
40. While the United States has made great strides in recent years, many advances in digital health technologies are still not broadly available, widely utilized, or well-tailored to meet the needs of all Americans. We seek comment on these concerns.	Many digital health technologies are not broadly available or adopted because they are often either seen as too expensive, too novel or of unproven or questionable value (clinically or economically). In some cases, these solutions are not adopted because they lack usability or the required workflow to support efficient clinical use or broad adoption beyond niche enthusiasts or edge use cases.
41. What are the emerging opportunities for investors, innovators, and entrepreneurs in the broadband health space and in the development of the next generation of connected health technologies and converged medical devices? We seek suggestions on any efforts that the Commission might undertake to support innovation and entrepreneurship in these areas. Are there	Emerging opportunities for investors, innovators and entrepreneurs in broadband health space are technologies that solve problems in healthcare interoperability, solutions that allow sharing of patient data between caregivers while retaining patient anonymity, and next generation devices that allow collection of patient data from the patient more accurately (clinically accurate). The next

| emerging or non-traditional stakeholders that should be part of the Commission's efforts? If so, please identify them and their respective roles in or contributions to the broadband health space. | generation of data analytics capabilities that will empower predictive and prescriptive models in medicine will be areas that will be ripe for investment and innovation, in particular with respect to expensive chronic disease states that often are tied to multiple comorbidities and significant costs to the healthcare system.

Other stakeholders that should be part of the Commission's efforts:
• Healthcare Informaticists
• Data Scientists
• Data Privacy Officers
• Chief Information Officers
• Device Manufacturers
    o Peripherals & wearables
    o Medical devices
• Telecommunications
    o Network Operators
    o IT Innovators
    o Equipment Manufacturers
• Mobile Device Manufacturers
• Health Information Technology
    o EMR Vendors
    o Health Information Exchange (HIE) Platforms
    o Cloud Platforms
    o Analytics Platforms
• Payers
    o Private
    o Government (e.g. Medicaid, Medicare)
• Providers/Physicians Regulators (e.g. FDA, FTC, HHS) |

Baxter truly appreciates the efforts of the FCC in providing this level of interest in identifying and taking action on ways to accelerate adoption and access to broadband-enabled health care solutions and advanced technologies. Thank you for the opportunity to provide comments to this public notice. If you have questions, please do not hesitate to contact either of the individuals listed below.

Respectfully submitted,

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